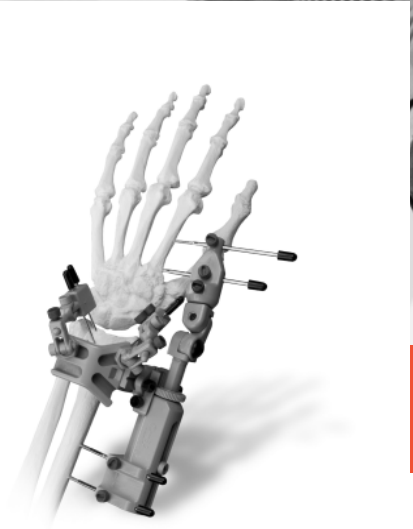




Wristore™*
Distal Radius
Fracture Fixator
Surgical
Technique



Visualize, stabilize, mobilize

Surgical Technique For Wristore™* Distal Radius Fracture Fixator

Instruments and surgical technique
developed in conjunction with

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Introduction

Fracture of the distal radius (DRF) is one of the most common types of wrist fracture. A DRF may be comminuted, and is accompanied by a fracture of the ulnar styloid process in about 50%-60% of cases.¹ If untreated, or inadequately treated, a DRF may result in shortening of the radius and dorsal inclination of its articular surface. Other potential complications of a DRF include unstable reduction, incongruity of joints, subluxation of the distal radioulnar joint, compression of the median nerve, ulnar nerve injury, entrapment of the flexor tendons, reflex sympathetic dystrophy, carpal malalignment, and nonunion.

The goal in the treatment of a DRF is to restore function while avoiding the potential complications. Understanding the mechanics of the fracture and the treatment options available is important when presented with a DRF. Accurate reduction and adequate immobilization are imperative in obtaining an optimal outcome.

Reduction can often be accomplished with traction and manual manipulation. Treatment generally includes immobilization with a splint or cast for simple fractures, while comminuted or severely displaced fractures may be treated with open reduction and internal fixation. An alternative surgical intervention is to use an external fixator, such as the *Wristore* Distal Radius Fracture Fixator, which provides a less invasive option for most distal radius fractures with or without comminution.

¹ BD, Browner, JB Jupiter, AM Levine, et al. *Skeletal Trauma, Basic Science, Management, and Reconstruction*, Vol 2, 3rd Edition. Saunders, 2003.

Distal Radius Fracture Classifications

The classifications of a DRF are based on the location of the fracture (intra-articular vs. extra-articular), and the presence or absence of ulnar fracture.

The *Wristore* Fixator is applicable for use in unstable and comminuted distal radial fractures (A2, A3, B2, C1, C2, and C3) which can be anatomically reduced with closed reduction methods. Refer to the AO Classification of Fractures of Long Bones for more specific information.

The *Wristore* Fixator should not be used where anatomic reduction cannot be achieved in a closed fashion or where volar instability exists.

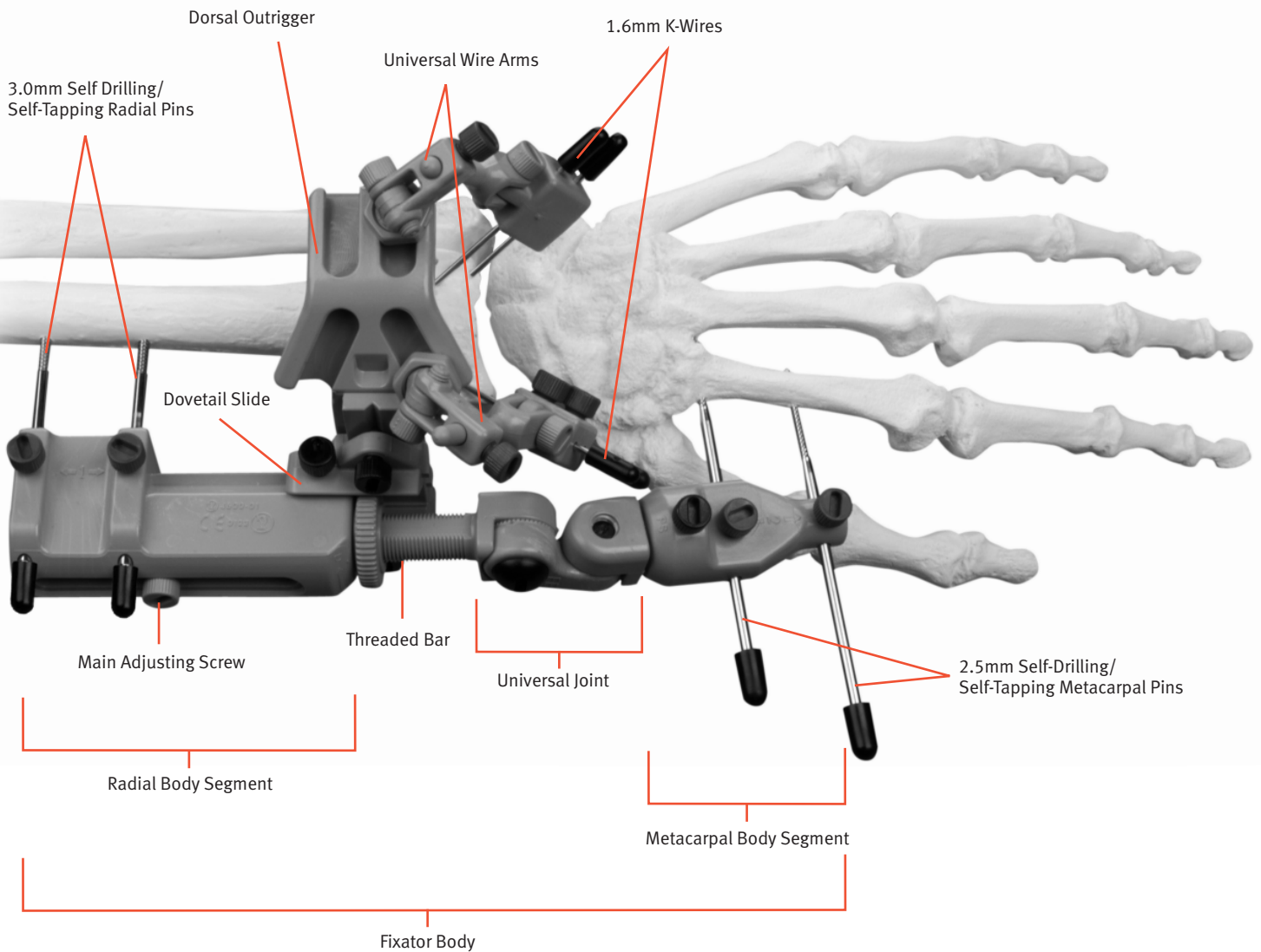
Design Rationale

The *Wristore* Fixator is indicated for external fixation of the upper extremity. In addition to providing stable fixation across the joint, the system is designed to capture and stabilize distal radial fragments. The design is intended to improve healing by providing better stability of the fracture fragments near the joint. This allows the option to begin early motion of the wrist to avoid “freezing” of the joint, and subsequent loss of range of motion due to soft tissue fibrosis or contracture.

Wristore Components

The *Wristore* Fixator is a modular system which facilitates spanning and non-spanning external fixation. The device consists of a Fixator Body and a Dorsal Outrigger with two Universal Wire Arms. The Fixator Body consists of four parts: the Radial Body Segment, a Threaded Bar, a Universal Joint, and the Metacarpal Body Segment.

The Dorsal Outrigger is a triangular extension that attaches to the Radial Body Segment by the Dovetail Slide. It contains slots that accept the Universal Wire Arms. These articulated arms are designed to secure K-wires to the Fixator.



Fixator Design

One of the key design goals was to combine the benefits of a multiplanar device with the ease of application of a unilateral device. More specific design goals included:

- Universal adjustability - The Fixator Body has multiplanar adjustability, allowing the surgeon to manipulate and reduce the fracture. Adjustments can be made to achieve:
 1. Compression/distraction - Slide the threaded bar proximally or distally within the Radial Body Segment or advance the thumb wheel on the Fixator Body. The main adjusting screw should be loosened while compressing/distractioning.
 2. Flexion/extension - Adjust the Universal Joint between the Radial and Metacarpal Body Segments.
 3. Radial/ulnar deviation - Adjusted via the Universal Joint.
 4. Pronation/supination - Rotate the distal segment at its articulation with the Universal Joint.
- Secure K-wires to Fixator Body – Dovetail Slide, Dorsal Outrigger and Universal Wire Arms work together to link fragments to the Fixator.
- Conversion from spanning to nonspanning fixation - when applied with both the Radial and Metacarpal Body Segments, the Fixator provides spanning fixation to immobilize the wrist joint. The modularity allows the Fixator to be applied as a spanning device, and then converted to a nonspanning device by removing the Metacarpal Body Segment. This allows for early, rehabilitative motion of the wrist while maintaining stable fixation.

NOTE: To use in a non-spanning configuration, the Dorsal Outrigger with K-wire fixation is required.
- Fixator Body components are numerically marked as follows:
 - 1 = Radial Body Segment
 - 2 = Metacarpal Body Segment
- Screws are color-coded as follows:
 - Blue = Pin locking screws
 - Black = Wrist position adjustment screws
 - Grey = Connection screws

Fixator Materials

The Fixator Body, Dorsal Outrigger, and Universal Wire Arms are made from molded Ultem material, a high strength polymer. This results in a completely radiolucent frame, and allows for an unobstructed radiographic image of the joint, the fracture, and the location of the pins and K-wires. The Ultem material was also chosen for its light weight, providing more comfort for the patient.

Pins and K-wires

The stainless steel pins are self-drilling and self-tapping so pre-drilling and tapping are not required for pin insertion. The system includes:

- Threaded 3.0mm Radial Pins
- Threaded 2.5mm Metacarpal Pins
- 1.6mm stainless steel K-wires
 - The system includes pin caps that will fit either size pins, and K-wire caps for the 1.6mm K-wires.

Instrumentation

The system includes three instruments, specifically designed for use with *Wristore* components, which are intended for single-patient use.

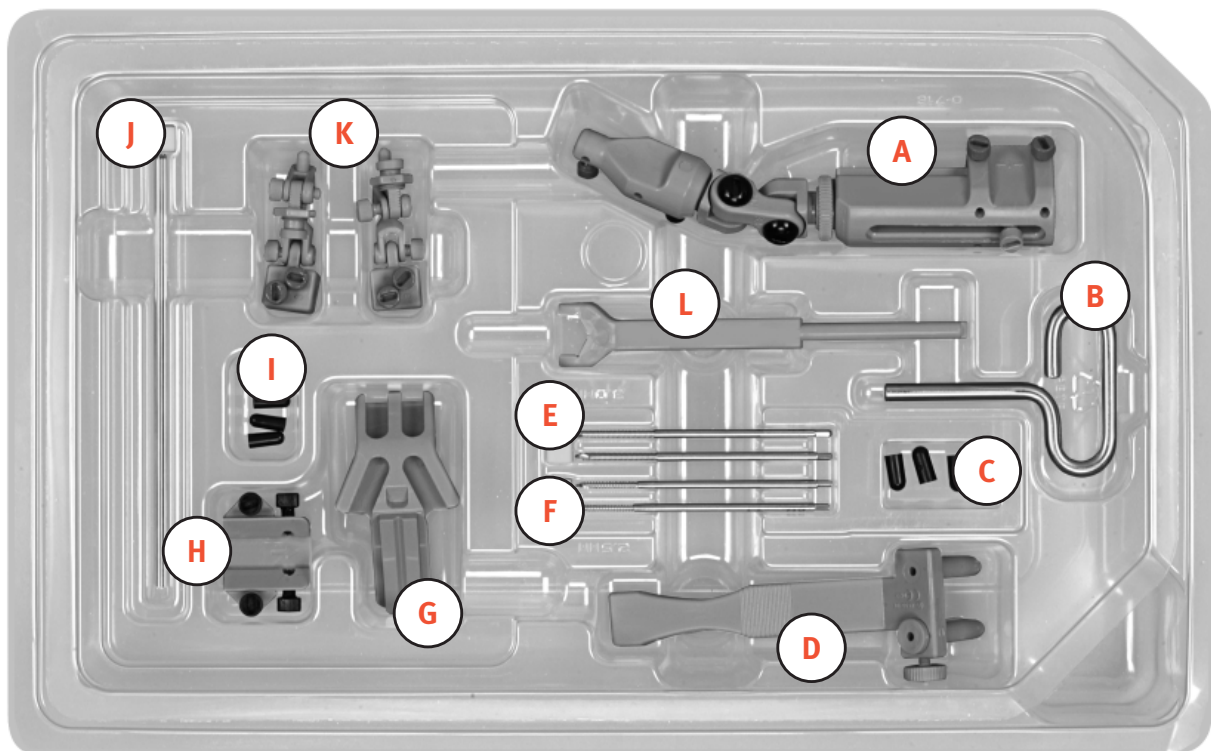
- Pin Inserter/Remover - This stainless steel T-handled device with a hex tip is used to drive and remove the threaded pins.
- Pin Guide - This guide is used for pin insertion and to protect soft tissue. The head has two sleeves that are spaced to match the spacing of the pin holes on the Fixator Body. One sleeve is fixed, while the other is adjustable so it will fit the specific patient anatomy. This sleeve can be moved up and down, and then locked into the appropriate position.
- Wrench/Driver - This instrument, has a blade tip that is used to tighten the locking screws on the *Wristore* construct, and an open hex end that is used to tighten and loosen the hex nut that secures the Universal Wire Arm to the Dorsal Outrigger.

Packaging

The *Wristore* Fixator is packaged in a sterile-pack kit that includes all Fixator components and instruments in one tray. The kit includes:

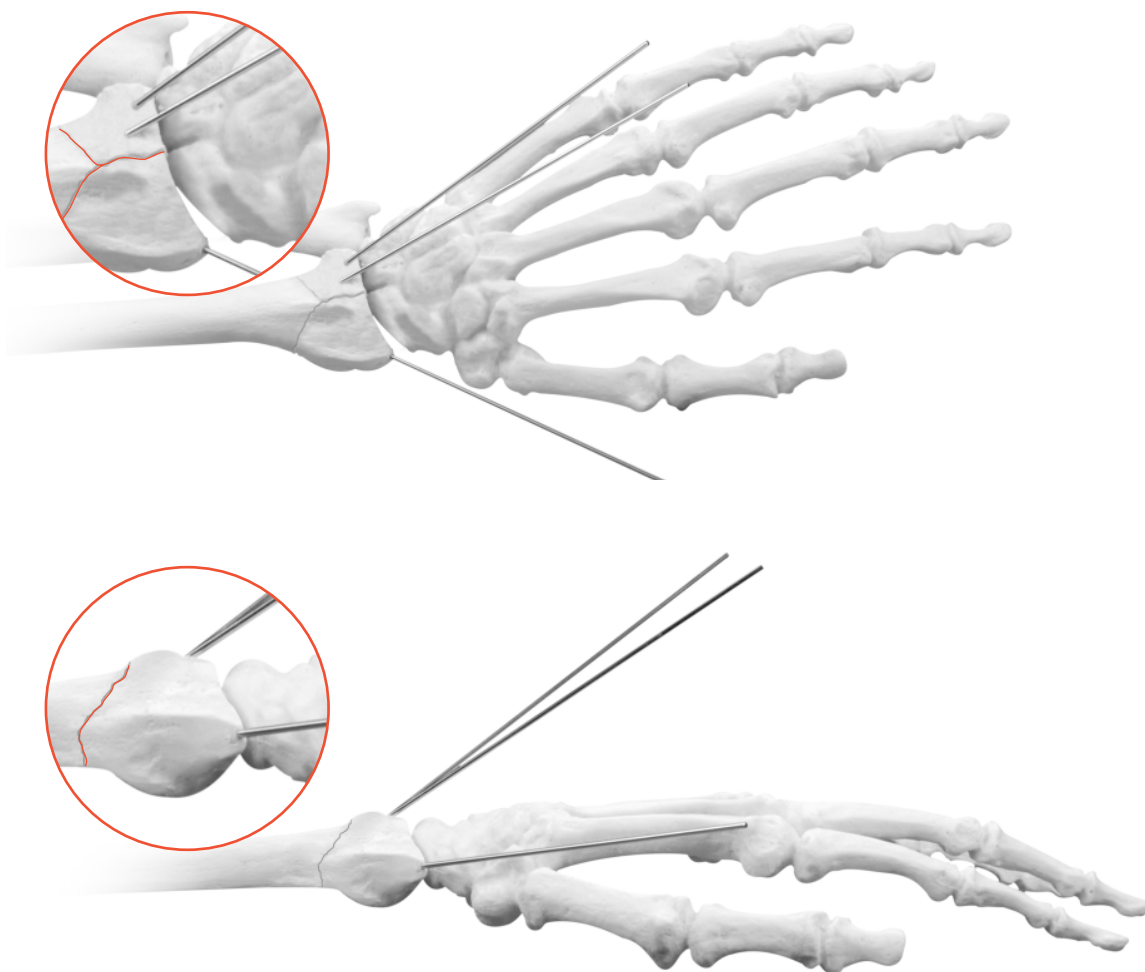
- A) Fixator Body
- B) Pin Inserter/Remover
- C) Five pin caps
- D) Pin Guide
- E) Two 3.0mm Radial Pins
- F) Two 2.5mm Metacarpal Pins
- G) Dorsal Outrigger
- H) Dovetail Slide
- I) Five K-wire caps
- J) Four 1.6mm K-wires
- K) Two Universal Wire Arms
- L) Wrench/Driver

The surgical technique steps are illustrated on the underside of the lid.



Preoperative Planning

Determine the appropriate K-wire positions, depending on fracture comminution and the location of major fragments. In general, biplanar pin placements which transfix the intact cortex opposite the fracture fragment result in the most stable configuration.²



² Naidu SH, Capo JT, Moulton M, Ciccone II W, Radin A. Percutaneous pinning of distal radius fractures: A biomechanical study. *J Hand Surg [Am]* 22: 252-57, 1997.